

Appl. No. : **10/063,510**
Filed : **May 1, 2002**

REMARKS

Claims 1-5 have been canceled without prejudice to, or disclaimer of, the subject matter contained therein. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the canceled claims in this or any other patent application. Accordingly, Claims 6-13 are presented for examination.

Correction of Inventorship under 37 CFR §1.48(b)

Applicant requests that several inventors be deleted, as these inventors' inventions are no longer being claimed in the present application as a result of prosecution. The fee as set forth in § 1.17(i) is submitted herewith.

Specification

The Examiner objected to the specification because it contains embedded hyperlinks. Applicants have amended the specification to address the Examiner's concern. In particular, Applicants have replaced the hyperlink with text that describes the location of the website. The amended text no longer constitutes browser executable code.

Information Disclosure Statement

On the IDS submitted September 5, 2002 Applicants inadvertently listed U.S. Patent No. 5,546,637 rather than U.S. Patent No. 5,536,637. Accordingly, Applicants submit herewith an Information Disclosure Statement listing the references submitted in the IDS of September 6, 2002 and corrected for the typographical error in the listing of U.S. Patent No. 5,536,637.

Claim Objections

The claims were objected to for improper numbering because they contain the letter "c." Applicants have amended the claims to delete the letter "c". The claims have also been amended to delete the figure numbers.

Rejections Under 35 U.S.C. §101

Claims 1-13 were rejected on the assertion that they are not supported by a specific asserted utility or a well established utility. The Examiner asserts that the disclosed utility is for "research purposes" where stimulation of TNF- α is desired and for "therapeutic treatment" of conditions in which enhanced TNF- α would be beneficial. The Examiner asserts that the specification does not teach how PRO263 functions and that the specification does not teach any

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particular condition where it beneficial to enhance levels of TNF- α . The Examiner further asserts that it is clinically more desirable to block the effects of TNF- α .

As attested in the accompanying Declaration of Paul Godowski, as of October 29, 1997, the filing date of the earliest application to which the present application claims priority, it was known that enhanced TNF- α levels are beneficial in treating certain conditions, such as cancer and viral infection, and in reducing the deleterious effects of ionizing radiation. As attested in the accompanying Declaration, references published prior to October 29, 1997 described the therapeutic benefits of enhancing TNF- α levels. In addition, while Applicants realize that actions taken by the PTO in other patent applications are not binding on the PTO with respect to the present application, Applicants note that numerous patents issued before October 29, 1997 relate to the therapeutic benefits of enhancing TNF- α levels, indicating that prior to October 29, 1997 the PTO found that inventions relating to the enhancement of TNF- α levels met the requirements of 35 U.S.C. §101.

The present specification describes how to make the claimed polypeptides. (See Paragraphs [0283]-[0309] and Examples 6-9 of the specification). As attested in the accompanying Declaration, the claimed polypeptides in turn can be used to treat the conditions known to be ameliorated by increasing TNF- α levels.

Furthermore, as acknowledged by the Examiner in the Office Action dated September 10, 2004 and attested in the accompanying Declaration, as of October 29, 1997 it was known that there are certain conditions in which it is beneficial to lower the levels of TNF- α . These conditions include rheumatoid arthritis and Crohn's disease. As attested in the accompanying Declaration, references published prior to October 29, 1997 described the therapeutic benefits of decreasing TNF- α levels. In addition, while Applicants realize that actions taken by the PTO in other patent applications are not binding on the PTO with respect to the present application, Applicants note that numerous patents issued before October 29, 1997 relate to the therapeutic benefits of decreasing TNF- α levels, indicating that prior to October 29, 1997 the PTO found that inventions relating to decreasing TNF- α levels met the requirements of 35 U.S.C. §101.

As described in Paragraphs [0361]-[0390] of the specification, the claimed polypeptides can be utilized to generate antibodies which neutralize the activity of the polypeptide. Pharmaceutical compositions comprising the antibodies can be prepared as described in

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Paragraphs [0400]-[0409] and Example 10 of the specification. As attested in the accompanying Declaration, such antibodies can be used to reduce the activity of the PRO263 polypeptide, thereby lowering TNF- α levels and achieving a therapeutic benefit.

For the foregoing reasons, Applicants maintain that the claimed polypeptides satisfy the requirements of 35 U.S.C. §101.

Rejections Under 35 U.S.C. §112

Claims 1-13 were rejected under 35 U.S.C. §112 on the assertion that because the claimed invention lacks utility, one skilled in the art would not know how to use the invention. For the reasons set forth above, Applicants maintain that the claimed polypeptides are useful. Accordingly, Applicants maintain that one skilled in the art would know how to use the claimed invention.

Claims 1-5 and 12-13 were rejected on the assertion that they encompass subject matter which was not described in the specification. The Examiner asserts that the claims encompass homologous polypeptides and do not require that the polypeptides possess any particular biological activity, any particular conserved feature or any other distinguishing feature.

Claims 1-5 have been canceled without prejudice and the dependency of Claims 12-13 have been amended to render them dependent on Claim 6. Accordingly, Applicants maintain that these rejections are moot.

Rejections Under 35 U.S.C. §102

Claims 1-5 and 12-13 were rejected on the assertion that they are anticipated by U.S. Patent No. 5,942,417 filed July 15, 1997 and claiming priority to a provisional application filed July 15, 1996. The Examiner asserts that the cited patent discloses a polypeptide which is 99.6% identical to SEQ ID NO: 6.

Claims 1-5 have been cancelled without prejudice and the dependency of Claims 12-13 has been amended to render them dependent on Claim 6. Accordingly, Applicants maintain that these rejections are moot.

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Conclusion

The present application is believed to be in condition for allowance, and an early action to that effect is respectfully solicited. Applicants invite the Examiner to call the undersigned if any issues may be resolved through a telephonic conversation.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: Dec. 9, 2004

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